Patent Claims

1. Composition for transdermal delivery of at least one immunogen to an individual comprising

a) said at least one immunogen
b) an occlusion vehicle and
c) an immunogen delivery system in the form of a PosIntro or an ISCOM.

2. Composition according to claim 1, wherein the occlusion vehicle is a pressure sensitive adhesive.

3. Composition for transdermal delivery of at least one immunogen to an individual comprising

a) said at least one immunogen
b) an occlusion vehicle in the form of a pressure sensitive adhesive and
c) an immunogen delivery system comprising at least one saponin and at least one sterol.

4. Composition according to any of the claims 1 to 3, wherein the transdermal delivery includes delivery through a skin surface or through a mucous membrane tissue.

5. Composition according to any of the claims 1 to 4, wherein the occlusion vehicle is a absorbing pressure sensitive adhesive.

6. Composition according to any of the claims 1 to 5, wherein the occlusion vehicle is a hydrocolloid adhesive.

7. Composition according to any of the claims 1 to 5, wherein the occlusion vehicle is a hydrogel adhesive.

8. Composition according to any of the claims 1 to 5, wherein the occlusion vehicle is a cross-linked hydrogel adhesive.

9. Composition according to any of the claims 1 to 8, wherein the immunogen and the immunogen delivery system is distributed preferably homogenously in the occlusion vehicle.

10. Composition according to any of the claims 1 to 8, wherein the immunogen and the immunogen delivery system is distributed on the surface of the occlusion vehicle.

11. Composition according to claim 1, wherein the occlusion vehicle is a non-adherent occlusion vehicle, and further comprising a secondary adhesive, being separated from the vehicle, for skin fixation.

12. Composition according to claim 11, wherein the occlusion vehicle is dried or lyophilised and contains a carrier comprising a hydrophilic polymer substance or a grease like composition.

13. Composition according to any of the claims 1 to 12, wherein the occlusion vehicle or the secondary adhesive is a covering, such as a pad, a patch, a dressing or the like.

14. Composition according to any of the claims 12 or 13 further comprising a reservoir of water or other appropriate solvent/diluent.

15. Composition according to claim 14, wherein the water reservoir can be broken and the water or solvent/diluent can be absorbed in the occlusion vehicle.

16. Composition according to any of the claims 1 to 15 further comprising a rate controlling membrane.

17. Composition according to any of the claims 1 to 16, wherein the immunogen and/or the immunogen delivery system is separated from each other.

18. Composition according to any of the claims 1 to 17 further comprising an enhancer for transdermal drug delivery.

19. Composition according to any of the claims 1 to 18, wherein the at least one immunogen is selected in such a way that the induced immunological response is directed against one or more antigens.

20. Composition according to claim 19, wherein said one or more antigens are derived from a microorganism, preferably a pathogenic microorganism, such as a virus, a bacteria, a parasite and/or a fungus, or from a non-microbial organism, e.g. from an animal, such as a vertebrate.

21. Composition according to any of the claims 19 or 20, wherein the immunogen and/or antigen are derived from a virus.

22. Composition according to claim 21, wherein said one or more antigens are synthetic antigens, antigens derived from said individual or antigens derived from any species.

23. Composition according to any of the claims 19 or 20, wherein said induced immunological response confers protection in said individual against a pathogenic microorganism which said antigen or antigens are part of.

24. Composition according to any of the claims 19-20 or 23, wherein said induced immunological response may act upon subsequent exposure of the individual to said pathogenic microorganism.

25. Composition according to any of the claims 19-20 or 23-24, wherein said induced immunological response is directed against a pathogenic component

produced by said pathogenic microorganism during infection of said individual, e.g. bacterial toxins, such as tetanus toxin.

26. Composition according to any of the claims 1 to 25, wherein the immunogen and/or antigen comprise or consist of

i) one or more identical or different polypeptides and/or peptides, which polypeptides and/or peptides optionally comprise posttranslational modifications,
ii) one or more identical or different lipopeptides, such as polypeptides and/or peptides chemically linked to a lipid group,
iii) one or more identical or different nucleic acid sequence or sequences, which may encode polypeptides and/or peptides, or
iv) one or more identical or different polysaccharides and/or oligosaccharides,

or combinations thereof, and wherein the immunogen and/or antigen may further be processed into fragments.

27. Composition according to any of the claims 1 to 26, wherein the immunogen and the immunogen delivery system is comprised within a vaccine formulation.

28. Composition according to claim 3, wherein the immunogen delivery system is a PosIntro or an ISCOM.

29. Composition according to any of the claims 1 to 28, wherein the immunogen delivery system is a complex comprising:

i) at least one first sterol and/or at least one second sterol,

wherein the at least one second sterol is capable of contacting a foreign antigen, preferably a nucleic acid by means of an interaction selected from an electrostatic interaction and a hydrophobic interaction, and
wherein the at least one first sterol and/or the at least one second sterol is capable of forming a complex with at least one first saponin and/or at least one second saponin, and

ii) at least one first saponin and/or at least one second saponin,

wherein the at least one second saponin is capable of contacting a genetic determinant by means of an interaction selected from an electrostatic interaction and a hydrophobic interaction, and
wherein the at least one first saponin and/or the at least one second saponin is capable of forming a complex with at least one first sterol and/or at least one second sterol, and optionally

iii) at least one contacting group for contacting a genetic determinant by means of an interaction selected from an electrostatic interaction and a hydrophobic interaction,

with the proviso that the at least one contacting group is present when no second sterol is present in the complex and further optionally

iv) at least one lipophilic moiety.

30. Process for the preparation of a composition according to any of the claims 1 to 29, comprising the steps of introducing the immunogen and the immunogen delivery system, which are optionally comprised within a vaccine formulation, into the matrix of the occlusion vehicle or on its surface by dispersion or soaking in a solution of the vehicle or by applying to its surface,

and optionally sterilising and/or drying and/or seal packaging the composition.

31. Process according to claim 30 further comprising the step of drying or lyophilisation or the immunogen and the immunogen delivery system before introducing into the vehicle.

32. Process according to any of the claims 30 or 31 further comprising the step of adding one or more enhancers for transdermal drug delivery and/or one or more plasticizers.

33. Construct comprising a composition according to any of the claims 1 to 29.

34. Construct according to claim 33, having one or more compartments.

35. Construct according to any of the claims 33 or 34 having at least two compartments, wherein a first compartment comprises a lyophilised pad comprising the immunogen and the immunogen delivery system and a second compartment comprises water or other appropriate solvent/diluent.

36. Construct according to any of the claims 33 to 35 comprising at least two separate components.

37. Method for generating an immunological response in an individual wherein a composition according to any of the claims 1 to 29 is administered to said individual.

38. Method for treating or preventing a condition of illness in an individual, e.g. a disease caused by infection of said individual by a pathogenic microorganism, wherein a composition according to any of the claims 1 to 29 is administered to said individual.

39. Method for vaccination of an individual wherein a composition according to any of the claims 1 to 29 is administered to said individual.

40. Use of an immunogen for the preparation of a composition for transdermal delivery of said immunogen comprising an occlusion vehicle.